

Remarks

Several of the drawings are amended herein to include proper labeling and presentation. The specification also is amended to reflect these changes to the drawings. These amendments do not represent new matter.

Claims 37 and 44 are amended herein to include the additional limitation of claims 43 and 50, respectively. Claims 43 and 50 are therefore canceled herein. Applicant reserves the right to pursue the subject matter of previous claims 37 and 44 in future prosecution in this or a related application.

I. Election/Restrictions

The Examiner has acknowledged Applicant's traversal of the restriction requirement but has deemed the requirement proper and therefore FINAL. The Examiner asserts that "because each of the recited sequences represents a non-overlapping fragment of a larger sequence and each fragment could be embedded within other patentably distinct proteins, a separate search is required for each possible fragment." Applicant respectfully disagrees with this assertion.

Because all of the recited sequences are within a single, larger sequence, the Examiner can search using the entire larger sequence as a query. The "hits" could then be analyzed to determine if any correspond to the peptides recited in the claims without a **serious** burden on the Examiner. Furthermore, even if patentably distinct proteins may contain a recited fragment embedded within it, the claims recite compositions comprising and methods using "a peptide **consisting essentially of** a tau amino acid sequence selected from the group consisting of ..." Any patentably distinct protein containing a recited fragment would "comprise" the peptide sequence and not "consist essentially of" the peptide sequence. Thus, a separate search is not required for each recited sequence.

As stated in MPEP § 803.02,

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner **must** examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions.

As discussed above, the peptide fragments are closely related in that they are all contained within the same protein (tau). Furthermore, the members of the group are closely related in that they contain serine or threonine residues in such

a context (Ser-Pro, Thr-Pro, Lys-Xxx-Gly-Ser) such that they may be phosphorylated in Alzheimer tau protein. Given these relationships between the peptides, a search and examination of the entire claim can be made without serious burden. Thus, the Examiner must examine all the members of the Markush group.

Moreover, should the Examiner maintain that search and examination of the entire Markush group would be a serious burden, Applicant directs the Examiner's attention to MPEP § 803.02. As indicated therein, "it is improper for the Patent Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, (CCPA 1980). Unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. When examining the entire Markush group would create a serious burden on the examiner and unity of invention exists among the members of the Markush group, the examiner should request an "election of species" to which the application would be limited in the absence of an allowable generic claim. See MPEP §§ 803.02 and 806.04(a)-(i).

Unity of invention exists among the members of the Markush group. The peptides included within the Markush group share the common utility of being useful in producing antibodies to regions of the tau protein that the inventors have shown are useful in distinguishing between normal tau protein and Alzheimer tau protein. Moreover, members of the Markush group share a substantial structural feature in that they are all peptide fragments of tau protein that contain a serine or threonine residue in a phosphorylatable context (Ser-Pro, Thr-Pro, Lys-Xxx-Gly-Ser) within the tau protein. Thus, unity of invention exists amongst the members of the Markush group. Therefore, if the examiner maintains that examining the entire Markush group would create a serious burden, the Examiner should request an "election of species" to which the application would be limited in the absence of an allowable generic claim.

Applicant respectfully requests that the Examiner reconsider the restriction requirement or, in the least, request an "election of species."

II. Drawings

Applicant provides herewith replacement drawings containing proper presentation and identification. The drawings, along with the amendments to the specification, are identical to those presented or made in the parent application Ser. No. 08/244,603, which

issued as U.S. Patent No. 6,200,768 on March 13, 2001. Reconsideration of the drawings is respectfully requested.

III. Specification

Applicant amends the specification herein to replace Table 1 on page 87. The replacement Table complies with 37 C.F.R. 1.58(c) with respect to font size. Reconsideration of the specification is respectfully requested.

IV. Rejections under 35 U.S.C. § 102

Despite the use of "consisting essentially of" in the present claims, the rejection asserts that the pending claims encompass an immunogenic composition comprising the entire tau protein of SEQ ID NO:1. Applicant respectfully disagrees with this assertion. According to MPEP § 2111.03, "consisting essentially of" limits the scope of a claim to the specified materials and those that do not materially affect their basic and novel characteristics. The MPEP further states that "consisting essentially of" should only be construed as "comprising" for purposes of searching or applying prior art under 35 U.S.C. 102 or 103 absent a clear indication in the specification or claims of what the basic and novel characteristics actually are. The Examiner did not contend that the specification or claims lacked a clear indication of what the basic and novel characteristics are. Rather, the Examiner defaulted straight to the "comprising" construction. ("Due to the use of transitional phrase "consisting essentially of" the instant claims encompass an immunogenic composition comprising the entire tau protein of SEQ ID NO:1") Absent a finding by the Examiner that the specification or claims lacked a clear indication of what the basic and novel characteristics of the peptide fragments are, the use of "consisting essentially of" in the present claims should not be construed as "comprising."

Nonetheless, irrespective of the construction of the term "consisting essentially of," the present claims recite that the peptide is conjugated to a carrier protein. Neither Kosik nor Vooheis describe conjugation of a tau peptide to a carrier protein. Thus, Neither Kosik nor Vooheis anticipate the currently pending claims. Applicant respectfully requests withdrawal of the rejection of the claims under 35 U.S.C. § 102.

IV. Double Patenting

As indicated above, Applicant asks for reconsideration of the restriction requirement. Withdrawal of the restriction requirement would render the Double-

Patenting rejection moot. Thus, prior to addressing the Double-Patenting rejection, Applicant awaits the Examiner's decision on the request for reconsideration.


CONCLUSION

All currently pending claims are allowed or are in condition of allowance. Applicant respectfully requests reconsideration of the pending claims. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, she is encouraged to contact the undersigned attorney at the number indicated below.

Respectfully submitted,

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January 30, 2004